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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,965	11/17/2000	Elizabeth M. Denholm	IT 106	7982

23579 7590 05/20/2003

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EXAMINER
MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
1654	16

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,965	DENHOLM ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

The election of species of record is maintained.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support for the term, "an established disorder requiring angiogenesis". Nowhere in the specification can such support be found.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing tumor cell growth using a chondroitinase, does not reasonably provide enablement for treating an established disorder requiring angiogenesis with the enzyme. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for reducing tumor cell growth using a chondroitinase, but is not enabled for treating an established disorder requiring angiogenesis with the enzyme.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test if an established disorder requiring angiogenesis can be treated with the enzyme (chondroitinase).

Applicant has only shown in their examples that the enzyme can be used to reduce tumor cell growth. With only knowing this, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only taught how to reduce tumor growth then to expect one of ordinary skill in the art to have understood that this would work with any and all disorders requiring angiogenesis is simply not valid on its face. Disorders such as arthritis and atherosclerosis, obesity in and of themselves are unrelated and one would not make the connection of them to the enzyme with only knowing that tumors could be reduced with the enzyme since different disorders are effected differently with different treatments. Simply because the enzyme worked on decreasing angiogenesis with tumors does not lead one of ordinary skill in the art to believe that it would also work with arthritis, for example.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by, "an established disorder requiring angiogenesis". How does the disorder require angiogenesis. Is not the disorder caused by the effects of angiogenesis ?

In claim 2, applicant still has not claimed the Markush group correctly. Before stating the enzyme in the third line from the bottom of the claim applicant needs to insert an "and".

Claim 4 is confusing since it is dependent on claim 8 which occurs later. Since claim 5 seems to cover this, claim 4 is probably unnecessary.

It still is not clear what applicant is referring to when they state, "these enzymes expressed from recombinant nucleotide sequences in bacteria". What "recombinant nucleotide sequences in bacteria" is applicant referring to ? This is not clear on the record. Applicant has only described how to isolate them non-recombinantly. The specification does not make this term clear. Without knowing what sequences applicant is referring to, it is simply unclear what the term means.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown.

Applicant argues that the enzyme is being used to treat a different disorder than that claimed. Fact is the reference is very explicit in its teaching of how the enzyme can be used. It sates on col. 4, lines 42-45 that the enzyme's pharmaceutical use is also applicable to the treatment of tumors. Knowing this, there is a clear teaching to use the enzyme to treat tumors as claimed by applicant.

Claims 1, 2, 4, 5, 9, 10, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi.

Applicants argue that the reference was interested in assessing tumor cells but the fact of the matter is that the reference is clear in that it states on tables 1 and 2 that chondroitinases clearly inhibit the growth of tumor cells which is what applicant's invention is. The reference has shown what applicant's claim and describe in their application. Applicant in the instant specification in example 9 also inject cells as the reference has done and then injected the enzyme, thus the invention and the reference are one and the same. Takeuchi clearly anticipates the invention because they do exactly what applicant has done and claimed.

Claims 1-5, 8-11, 24, 25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/01648.

Applicant has not addressed this reference in their 35 USC 102 arguments but did in the 35 USC 103 arguments. Applicant argues that the reference fails to mention "angiogenesis" but applicant's attention is drawn to page 5 of the reference. The

reference does mention angiogenesis and does teach that wound healing is inhibited and thus angiogenesis is decreased.

Claim Rejections - 35 USC § 103

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasisekharan et al. taken with Takeuchi, Brown or WO 96/01646.

Applicant argues that Sasisekharan does not teach using chondroitinases only heparinases. While this is true, it would have been obvious to use a chondroitinase since the other references clearly show that chondritinases are also successfully used to treat tumors.

Claims 1-11 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi, Brown or WO 96/01646.

This rejection is of record and was addressed above when talking about the references.

Applicant did not add any more arguments about the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
May 5, 2003